

~~Docket No.: Afan-003~~

p1
2. (Amended) The system of claim 1, wherein said interchangeable fiberoptic probe is selected from a shaped probe, a needle probe, a diffusor probe, a microscopic head probe, an endoscopic probe and a catheter probe.

B2
8. (Amended) The method of claim 8, wherein said comparing comprises comparing an area under a peak in said at least one selected absorption band in said first Fourier transform infrared spectrum to an area under a peak in said at least one selected absorption band in said second Fourier transform infrared spectrum.

REMARKS

Claim Objections

Applicant has amended claim 8 to comply with the Examiners request. As amended, claim 8 is believed to be in condition for allowance.

Claim Rejections - 35 U.S.C. § 112

Applicant has amended claim 2 to comply with 35 U.S.C. § 112. As amended, claim 2 is believed to be in condition for allowance.

Claim Rejections - 35 U.S.C. § 102(b) and 35 U.S.C. § 103

The Examiner has rejected claims 1 through 4 under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Kittrell et

Docket No.: Afan-003

al. (U.S. Patent No. 5,304,173). Applicant respectfully disagrees.

Anticipation

To anticipate a claim under 35 U.S.C. § 102, a single source must contain all of the elements of the claim. *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q.2d 1766, 1768 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

The Examiner contends that Kittrell discloses a system for analysis of biological samples as claimed in independent Claim 1 and dependent Claims 2-4. Applicant respectfully disagrees with the Examiner's contentions.

Kittrell et al. (US 5,304,173) discloses fluorescence spectral system comprising a laser catheter for controlled delivery (only for the delivery) of a laser beam to fibrous plaque and normal arterial wall for removing tissue. Spectroscopic diagnostics (in the limited visible (VIS) range 500-700nm) is used determine only what tissue is to be removed. This is not related to infrared (IR) systems for measurements of molecular composition and chemical bonds of living tissues. Applicant's optical fibers works for detection and testing of tissue at the molecular level.

Kittrell et al. Has disclosed completely different materials, shapes of fibers, and ending probes. Applicant uses unclad optical fibers for the tissue diagnosis.

Kittrell et al. works in the field of fiber optic laser ablation (evaporation) of tissue with the help of fiber optics as a delivery system and controlled variation of portion of light for removing tissue layer by layer. The main goal of the Kittrell is to provide a controlled fashion of removing tissue with the help of a laser catheter. Applicant's goal was to develop flexible IR fiber optic diagnosis system for noninvasive detection of the molecular composition of living tissue and body fluids in vivo and specifically for cancer testing and/or comparison of normal and malignant tissues.

Kittrell's invention is focused on an optical shield with various types of optical elements incorporated. Applicant's invention does not need any additional elements in the end of the optical fibers because the fibers are a measuring instrument (instead ATR prisms or other ATR elements) with the same signal/noise ratio (S/N) as any IR spectrometer has.

Figs. 19 and 20 of Kittrell shows a block diagram of linear array fiber selector system and Figs. 21-23 shows spectral detector or analyzer for limited UV/VIS spectral range without detailed composition of plagued tissue. It is only spectral diagnostics "yes" or "no" plague on partial intensity of fluorescence light (Fig. 26 A and B).

Docket No.: Afan-003

traditional UV/VIS spectroscopy is not a method for a fingerprint of different molecular groups and bonds.

On page 21 Kittrell states, "Whole arterial wall samples were placed in quartz cuvettes immersed in saline solution." It is not in vivo diagnostics, it is in vitro diagnostics. Kittrell's invention uses traditional methods of any diagnostics with routine sample preparations. Kittrell uses spectral analysis as a secondary step (without optical fibers). Applicant's system allows for the testing of samples without any cuvettes for spectral analysis. Applicant's system is free from routine sample preparation for spectral testing.

Kittrell focuses on "the degree of control in the tissue removal process." In other words - it is control of laser ablation (or controlling laser ablation) with the help of optical fibers for the delivery of an appropriate portion of light to tissue. The authors gave only one example of comparison of plaque and normal tissue (Fig.26A, B). Using of optical fibers for the delivery of light including IR light also was and is very popular applications for optical fibers. See p.7, bottom, where is 65

Kittrell does not disclose all the elements of claims 1-4, nor does Kittrell disclose all the elements arranged as in the claims, and therefore, claims 1-4 are not anticipated by Kittrell. Reconsideration and withdrawal of this rejection is respectfully requested.

Docket No.: Afan-003

Obviousness

“The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process ... The examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness ...” MPEP §2142. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest ***all the claim limitations***. MPEP § 2142 (emphasis added). Here, the reference does not teach or suggest all the claim limitations.

The Examiner states that it would be obvious to someone that spectral analysis of detected IR radiation can be performed with a standard Fourier spectrophotometer and that it would be obvious that catheter systems must include means for changing probes. The Examiner has stated that the reference does not teach or suggest all the claim limitations. Thus, Applicant’s system is not obvious under Kittrell.

Docket No.: Afan-003

Kittrell does not teach or suggest all the claim limitations of claims 1-4, and therefore, claims 1-4 are not obvious under Kittrell. Reconsideration and withdrawal of this rejection is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

The Examiner has rejected claims 1 through 4 under 35 U.S.C. § 103(a) as being unpatentable over Kittrell et al. (U.S. Patent No. 5,304,173) in view of Clift (U.S. Patent No. 5,452,716). Applicant respectfully disagrees.

"The legal concept of *prima facie* obviousness is a procedural tool of examination which applies broadly to all arts. It allocates who has the burden of going forward with production of evidence in each step of the examination process ... The examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness ..." MPEP §2142. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest ***all the claim limitations***. MPEP § 2142 (emphasis added). Here, the references when combined do not teach or

Docket No.: Afan-003

suggest all the claim limitations.

“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of the combination.” *In re Mills*, 916 F.2d 680; 16 U.S.P.Q. 2d 1430 (Fed. Cir. 1990).

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Monteffiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984).

The Examiner states that Kittrell teaches all the claim limitation of independent claim 1 except that Clift teaches the use of a Fourier spectrophotometer for detected radiation from a biological sample. However, Kittrell actually teaches away from Applicant's system by stating in column 5 lines 18-26 that Kittrell's invention *overcomes the disadvantages of bare fibers* whereas Applicant's teaches only the use of an optical fiber. Teaching away is the antithesis of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988). Thus, Applicant's system is not obvious under Kittrell.

As to claims 2 through 5, they all depend on claim 1. If an independent claim is found to be non-obvious, all claims depending therefrom are non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988).

Docket No.: Afan-003

Claims 6-10

The Examiner has rejected claims 6 through 10 under 35 U.S.C. § 103(a) as being unpatentable over Kittrell et al. (U.S. Patent No. 5,304,173) in view of Haaland et al. and in further view of Clift (U.S. Patent No. 5,452,716). Applicant respectfully disagrees.

Kittrell actually teaches away from Applicant's system by stating in column 5 lines 18-26 that Kittrell's invention *overcomes the disadvantages of bare fibers* whereas Applicant's teaches only the use of an optical fiber. Teaching away is the antithesis of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988). Thus, Applicant's claim 6 is not obvious under Kittrell.

As to claims 7 through 10, they all depend on claim 6. If an independent claim is found to be non-obvious, all claims depending therefrom are non-obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988).

CONCLUSION

For the foregoing reasons, Applicant submits that all of the claims in this application are in condition for allowance and Applicant respectfully requests reexamination of the present application, reconsideration and withdrawal of the present

Docket No.: Afan-003

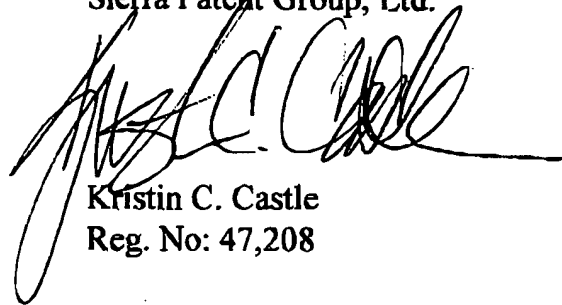
rejections. Should there be any further matter requiring consideration, the Examiner is invited to contact the undersigned counsel.

For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully submitted,
Sierra Patent Group, Ltd.

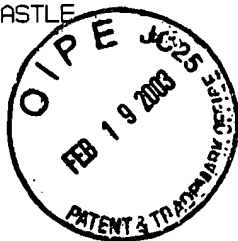
Dated:

2/13/03



Kristin C. Castle
Reg. No: 47,208

Sierra Patent Group, Ltd.
PO Box 6149
Stateline, NV 89449
(775) 586-9500



Docket No.: Afan-003

APPENDIX A - MARKED-UP CLAIMS

Kindly amend claims 2 and 8 as follows:

2. (Amended) The system of claim 1, wherein said interchangeable fiberoptic probe is selected from a shaped probe, a needle probe, a diffuser probe, a microscopic head probe, an endoscopic probe [or] and a catheter probe.

8. (Amended) The method of claim[58] 8, wherein said comparing comprises comparing an area under a peak in said at least one selected absorption band in said first Fourier transform infrared spectrum to an area under a peak in said at least one selected absorption band in said second Fourier transform infrared spectrum.

RECEIVED

FEB 21 2003

TECHNOLOGY CENTER R3700